

REMARKS

Applicants express their appreciation to Primary Examiner Glenn K. Dawson for the courtesy of an interview which was granted to the applicant's representative, Sanford T. Colb (Reg. No. 26,856). The interview was held at the Examiner's office at the USPTO on July 2, 2003. The substance of the interview is set forth in the Interview Summary, Paper No. 35, given to applicants' representative. According to that summary, agreement was reached that the claims may be amended to include a recitation of either the pair of oxygen delivery inlets (outlets) or the gas collection outlets (inlets) being embodied in a pair of nares. The Examiner indicated that this limitation appeared to distinguish over Derrick. The applicants, after due consideration of this amendment, have preferred to amend claim 29 to recite that at least the at least two exhaled gas inlets are embodied in a pair of prongs, and respectfully submit that this claim language recites structure which distinguishes over Derrick in a manner similar to that agreed at the interview. Furthermore, the term "prongs" is used, rather than the equivalent "nares," prongs being the term used throughout the specification.

Furthermore, applicants have cancelled without prejudice claims 37-38 and 49-50, and part of the matter thereof is now recited in new claims 53-55 and 57-59. Applicants have carefully studied the outstanding Office Action. The Examiner's indication that claims 31, 32, 43, 44, 49 and 50 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, to include all of the limitations of the base claim and any intervening claims is gratefully acknowledged. Since applicants understand, as an outcome of the interview, that the respective base claims of these dependent claims will now be allowed, applicants prefer to leave these claims as dependents. The present amendment is intended to be fully responsive to all

points of rejection raised by the Examiner, and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Claim rejections - 35 USC § 112

Former Claims 29 - 52 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In claims 29 and 41, the Examiner asserts that the use of "reduced" is indefinite given no reference point, and that it is unclear relative to what the force is reduced. Applicants have amended claims 29 and 41 to recite ".....said oxygen inlets being such as to provide an oxygen stream in the region of the nostrils having a force **sufficiently low that** exhaled gases collected from said nostrils are generally undiluted by said oxygen. (Emphasis added.) Applicants submit that the level of the force of the oxygen stream is now referred to the effect which such a stream has on the exhaled gases collected from said nostrils, thus removing the asserted indefiniteness of claims 29 and 41.

In claims 30 and 32, the Examiner has stated that the phrase "are such as create" is vague and confusing language. Applicants have amended claims 30 and 32 to recite "..... are such as to create," thereby correcting the vague and confusing language.

In claim 44, the Examiner has stated that the reference of "42,d" is unclear. Applicants have amended claim 44 to recite "42," thereby correcting the lack of clarity.

Claim rejections - 35 USC § 102

Former Claims 29, 30, 37-42, 51 and 52 have been rejected under 35 USC § 102(b) as being anticipated by US 5,046,491 to Derrick. The Examiner states that "Derrick discloses a device and method of use including a tube with a first nasal prong for receiving exhaled gases; an oxygen delivery tube 98 having two inlets (one of which is the inlet into cannula connected to tube 98 at region 18 in Fig. 4), and the other can be any of 96, 100, 108, 104."

Applicants respectfully submit that the device and method described in Derrick differ from that of the present claimed invention in a number of aspects. Some of these aspects are discussed in the description of the Derrick cannula in the present application, as presented on page 15 in relation to Fig. 3 of the present specification.

To the best of the applicants' understanding of the Derrick patent, as described in col. 8, lines 8-14, and shown in Fig. 4 of Derrick, the device uses a single nasal prong 92/104 (called a cannula in Derrick) to supply oxygen to one nostril of the patient, and another single nasal prong 94/106 for collecting exhaled gases from the second nostril of the patient. As a result of this structure, the oxygen delivery nasal prong 92/104 generally produces a forceful stream of oxygen directly within the nostril of the patient, which firstly may be uncomfortable for the patient, but more importantly, may also penetrate to the second nostril of the patient, where the stream may dilute the exhaled breath being collected by the nasal collection prong 94/106 in the second nostril, and result in the collection of inaccurate breath samples.

Furthermore, the described structure of the Derrick device is asymmetric relative to the patient's nostrils, with oxygen delivery being provided to one nostril and breath collection being performed at the other.

Additionally, no embodiment is described or suggested by Derrick which would enable oxygen supply and breath collection to be performed at the same nostril.

In contrast to device described in the Derrick patent, amended claim 29 of the present application recites:

"A cannula for the collection of exhaled gases from a patient having nostrils, and for the supply of oxygen to the patient, comprising:

a tube having **at least two exhaled gas inlets** for the collection of said exhaled gases from the patient;

at least one oxygen delivery tube configured to be located near the nostrils of the patient; and

at least two oxygen outlets associated with said at least one oxygen delivery tube;

said cannula being configured such that **said oxygen outlets are disposed generally symmetrically relative to the nostrils of the patient**, such that said oxygen flows from said at least one oxygen delivery tube through said oxygen outlets into the region of **both** of the nostrils of the patient, said oxygen outlets being such as to provide an oxygen stream in the region of the nostrils **having a force sufficiently low that exhaled gases collected from said nostrils are generally undiluted by said oxygen**, at least said at least two exhaled gas inlets being embodied in **a pair of nasal prongs**." (Emphasis added.)

Support for the first and the last amended recitation in amended claim 29, as designated in bold type above, is to be found in the specification on page 7, lines 2-3, and in Fig. 6A, for the next two amended recitations in amended claim 29, in the specification on page 5, lines 15-18, and in Fig. 6A. The fourth amended recitation above is merely one of changed style, to avoid any indefiniteness, and is not of any substantive nature.

To the best of applicants' understanding, nowhere is there shown or suggested in Derrick, any of the five elements of amended claim 29 of the present application, outlined above in bold type. Applicants therefore respectfully submit that amended claim 29 is not taught or suggested by the Derrick patent, and is believed to be allowable.

Applicants also respectfully submit that amended claim 41, being an method claim equivalent to apparatus claim 29, should, for the same reasons, also believed to be allowable.

Claims 30 to 40, amended where appropriate, are dependent on amended claim 29, and recite additional patentable matter. Claims 30 to 40 are therefore also believed to be allowable.

Claims 42 to 52, amended where appropriate, are dependent on amended claim 41, and recite additional patentable matter. Claims 42 to 52 are therefore also believed to be allowable.

Claim rejections - 35 USC § 103(a)

Former Claims 33-36 and 45-48 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Derrick '491 in view of Dickerman et al. (U.S. Patent 5,113,857). The

Appln. No. 10/033,387
Amdt. dated August 7, 2003
Reply to Office Action of February 12, 2003
Attorney Docket No. 4026-4005US1

Examiner states that: "Derrick discloses the invention as claimed with the exception of the filter in one of the inlets. Dickerman discloses that it was known to provide filters in the oxygen delivery line. It would have been obvious to place a filter in the oxygen delivery line in order to ensure breathing gas free from contaminants."

Applicants respectfully submit that the Examiner's base assertion, that Derrick discloses the invention as claimed with the exception of the filter in one of the inlets, is incorrect, for the reasons stated above in connection with the Examiner's rejections under 35 U.S.C. 102(b). Therefore, no combination of other art in combination with Derrick can render claims 33-36 and 45-48 as obvious.

Furthermore, applicants wish to add that nowhere are **filters** recited in any of the claims of the present invention. On the contrary, in claims 33-36 and 45-48, **screens** are recited, and their function is quite different from the filters described in the Dickerman patent cited by the Examiner. The function of the screens of the present claimed invention, as described on page 20, lines 14-21 of the specification, is to reduce the force of the delivered oxygen stream, so that an oxygen cloud is created near the nostrils of the patient. Such screens therefore, are substantially different from the filters of the Dickerman patent.

For the reasons set forth above, applicants respectfully submit that claims 33-36 and 45-48 of the present invention are not rendered obvious in the light of Derrick and Dickerman, and withdrawal of these grounds of rejection of those claims is respectfully requested.

New claims

The applicants have filed new dependent claims 53 to 56, dependent ultimately on claim 29, and new dependent claims 57 to 60, dependent ultimately on claim 41, which recite further patentable matter. Claims 53 to 55 recite various embodiments where at least one of the oxygen outlets is in the form of a second nasal prong substantially shorter in length than the exhaled gas inlet nasal prongs. Support for the subject matter of these claims is to be found in the specification on page 9, first paragraph, and in Figs. 8A and 8B and associated description on page 21, and in the material of canceled claims 37 and 38. Claim 56 recites an embodiment wherein a portion of the oxygen tube is formed of a substantially porous material. Support for this claim is to be found in the specification on page 9, lines 10 to 13. New claims 57 to 60 are method claims corresponding to the apparatus claims 53 to 56.

Conclusion

Applicants therefore respectfully submit that, in the light of the remarks set forth above, all of the amended and originally filed claims 29-52, and new claims 53 to 60 are novel and unobvious over the prior art cited by the Examiner, and recite patentable subject matter. Claims 29-60 are therefore all believed to be allowable. Reconsideration and prompt allowance of Claims 29, 30-36, 39-48, and 51-60 are therefore respectfully requested.

Respectfully submitted,



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